



Docket No.: ABB1130P0900S

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:) Novel Formulations Comprising Lipid-
J. Patel et al.) Regulating Agents
Serial No. 09/524,113)
Filed: March 13, 2000) Group Art Unit: 1617
Examiner: Mojdeh Bahar

TRANSMITTAL LETTER

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Final Office Action dated May 3, 2003, Applicants filed a Notice of Appeal on August 27, 2003. Applicants submit herewith three (3) copies of the Appeal Brief as required.

Respectfully submitted,

WOOD, PHILLIPS, KATZ, CLARK &
MORTIMER


Martin L. Katz, Reg. No. 25,041


Date: October 15, 2003

500 W. Madison Street
Suite 3800
Chicago, IL 60661-2511
(312) 876-1800



37 CFR 1.8
CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service, as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on October 15, 2003.


Rebecca J. Willis

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BRIEF ON APPEAL

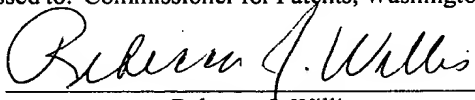
Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the May 3, 2003 Final Office Action issued in the present application, Applicants filed a Notice of Appeal on August 27, 2003. This is the Appellants' Brief on Appeal filed pursuant to this Appeal.

37 CFR 1.8
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Rebecca J. Willis

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BRIEF ON APPEAL

I. REAL PARTY IN INTEREST

The real party in interest is Abbott Laboratories, the Assignee of all rights and interests in the present application.

II. RELATED APPEALS AND INTERFERENCES

There are no known related pending appeals or interferences pending with regard to this application. However, Notices of Appeal have been filed in application Serial Numbers 09/215,831, 09/216,242 and 09/216,247 which are directed to related subject matter and have been rejected over the same primary reference.

III. STATUS OF CLAIMS

The present application was filed with claims 1 to 18. Claim 19 has been added and claims 2, 4-6 and 13 to 18 have been canceled. Claims 1, 3, 7-12 and 19 are at issue in this appeal. There is one outstanding ground of rejection as follows:

A. Claims 1, 3, 7-12 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lacy et al. (U.S. Patent No. 5,645,856) ("Lacy").

IV. STATUS OF AMENDMENTS

As noted above, claims 2, 4-6 and 13-18 have been canceled. Claim 1 has been amended four times and claims 3, 7, 9, 11 and 16-18 have been amended once. Claims 1, 3, 7-12 and 19, as presently amended, are set forth in the Appendix.

V. SUMMARY OF THE INVENTION

The present invention is directed to a composition consisting of a fibrate dissolved in at least one oil with one specified emulsifier.

The compositions of the present invention result in increased drug solubility, oral bioavailability and half-life compared to commercially available formulations.

VI. ISSUES PRESENTED:

A. Are claims 1, 3, 7-12 and 19 patentably nonobvious over Lacy under 35 U.S.C. §103(a)?

VII. GROUPING OF CLAIMS

The claims are grouped in two (2) groups as follows:

- A. claims 1, 3, and 7-12; and
- B. Claim 19.

VIII. ARGUMENT

A. Rejection of claims 1, 3, 7-12 and 19 under 35 U.S.C. §103(a).

Claims 1, 3, 7-12 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lacy.

Each claim is limited to a composition consisting essentially of a fibrate dissolved in at least one oil with one specified emulsifier. Lacy does not render the claims unpatentable because Lacy requires surfactants that are different in character than the specifically claimed emulsifiers of the present invention.

As set forth in claim 1 and those claims dependent thereon, the transition phrase “consisting essentially of” includes the listed ingredients and is only open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. PPG Industries, Inc. v. Guardian Industrial Corp., 156 F.3d 1351, 48 USQ2d 1351 (Fed. Cir. 1998).

As set forth in claim 19, the transition phrase “consisting of” applies to the claim closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith. Ex parte Davis and Tuukkanen, 80 U.S.P.Q. 448, 450 (Bd. App. 1949), Mannessman Demag Corp. v. Engineered Metal Products Co., Inc., 793 F.2d 1279, 230 U.S.P.Q. 45 (Fed. Cir. 1986), Vehicular Technologies Corp. v. Titan Wheel International, Inc., 54 U.S.P.Q.2d 1841, 1845 (Fed. Cir. 2000).

As noted above, claims 1, 3 and 7-12 are directed to compositions consisting essentially of a fibrate dissolved in at least one oil with one specified emulsifier and to their

use to treat hyperlipidemia and claim 19 is directed to compositions consisting of a fibrate dissolved in at least one oil with one specified surfactant.

In contrast, Lacy discloses a carrier for hydrophobic drugs comprising a digestible oil and a pharmaceutically acceptable surfactant component for dispersing the oil *in vivo*. (ABSTRACT.) The surfactant component comprises a hydrophilic surfactant component, that does not substantially inhibit the lipolysis of the oil, preferably a mixture of a hydrophilic surfactant component which substantially inhibits the *in vivo* lipolysis of a digestible oil and a lipophilic surfactant component capable of at least substantially reducing the inhibitory effect of the hydrophilic surfactant component (column 3, lines 38-67).

Lacy teaches away from the claimed invention. A reference must be considered for all that it teaches, including disclosures that diverge and teach away from the invention. In re Dow Chem. Co., 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988). A reference teaches away when a person of ordinary skill, upon reading it, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the inventor. Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH 139 F.3d 877, 45 USPQ2d 1977 (Fed. Cir. 1998).

The present invention, as set forth in claim 1, provides a composition consisting essentially of a fibrate dissolved in at least one oil with one selected emulsifier. The emulsifiers used in the present invention do not exhibit or demonstrate the property of not substantially inhibiting the lipolysis of the oil. The emulsifier does not contain a hydrophilic surfactant component that substantially inhibits the *in vivo* lipolysis of an oil, and a

lipophilic surfactant component capable of at least substantially reducing said inhibitory effect of said hydrophilic surfactant component as provided by Lacy. Fibrates are simply dissolved in at least one oil with one selected emulsifier; there is no requirement for a surfactant that does not substantially inhibit lipolysis. The inclusion of a surfactant that does not substantially inhibit lipolysis of an oil is an important property of Lacy's compositions (column 3, lines 38-45 and claim 1); this is NOT a property of the presently claimed invention. Thus, the present compositions would not be obvious in view of Lacy.

Claimed subject matter would not be obvious when upon reading a reference, a person of ordinary skill would be led in a direction divergent from the path taken by the inventor. Monarch, *supra*. For the above stated reasons, claims 1, 3, 7-12 and 19 are patentably nonobvious over Lacy under 35 U.S.C. §103(a) and this rejection should be reversed.

For the reasons herein, Lacy does not render claims 1, 3, 7-12 and 19 unpatentable under 35 U.S.C. §103(a). Reversal of this rejection is respectfully requested.

IX. CONCLUSION

The rejection of claims 1, 3, 7-12 and 19 should be reversed and this application should be remanded for the issuance of a Notice of Allowance.

Respectfully submitted,

WOOD, PHILLIPS, KATZ,
CLARK & MORTIMER

By Martin L. Katz
Martin L. Katz
Reg. No. 25,011

Date: October 15, 2003

Citicorp Center
500 West Madison Street
Suite 3800
Chicago, IL 60661-2511
(312) 876-1800

APPENDIX - CLAIMS AT ISSUE

Claim numbers 1, 3, 7-12 and 19 are at issue and read as follows:

1. A composition consisting essentially of a fibrate dissolved in at least one oil with one emulsifier selected from the group consisting of polyoxyethylene sorbitan fatty acid derivatives, sorbitan fatty acid derivatives, polyoxyl-35-castor oil, castor oil ethoxylates, hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, and d-alpha tocopheryl polyethylene glycol 1000 succinate wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.

3. A composition of claim 1 wherein the fibrate is fenofibrate.

7. A composition of claim 1 wherein at least one or more of said emulsifiers is selected from the group consisting of phospholipids, polyoxyethylene sorbitan fatty acid derivatives, sorbitan fatty acid derivatives, polyoxyl-35-castor oil, castor oil ethoxylates, hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, d-alpha tocopheryl polyethylene glycol 1000 succinate and combinations thereof.

8. A composition of claim 7 wherein at least one or more of said emulsifiers is polyoxyethylenesorbitan fatty acid derivatives, sorbitan fatty acid derivatives and polyoxyl-35-castor oil.

9. A composition of claim 1 wherein said oil is selected from the group consisting of soybean oil, coconut oil, corn oil, palm kernel oil, cottonseed oil, olive oil, peanut oil, safflower oil and sesame oil.

10. A composition of claim 9 wherein said oil is soybean oil.

11. A composition of claim 1 further comprising a co-solvent.

12. A composition of claim 11 wherein said co-solvent is ethanol, propylene glycol or polyethylene glycol.

19. A composition consisting of a fibrate dissolved in at least one oil with one emulsifier selected from the group consisting of polyoxyethylene sorbitan fatty acid derivatives, sorbitan fatty acid derivatives, polyoxyl-35-castor oil, castor oil ethoxylates, hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, and d-alpha tocopheryl polyethylene glycol 1000

succinate wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.